

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 101 440 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
23.05.2001 Bulletin 2001/21

(51) Int Cl.7: A61B 5/021

(21) Application number: 99122743.0

(22) Date of filing: 16.11.1999

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

- Frick, Gerhard
6800 Feldkirch (AT)
- Yen, Chung-Yueh
Taichung 404 (TW)

rw
jz
me
ms
rk

✓
✓
✓
✓

(71) Applicant: Microlife Corporation
Taipei (TW)(74) Representative: Hepp, Dieter et al
Hepp, Wenger & Ryffel AG,
Friedtalweg 5
9500 Wil (CH)(72) Inventors:
• Forstner, Klaus
71679 Asperg/Württemberg (DE)

(54) Non invasive blood pressure monitor

(57) A blood pressure measuring device is operable in a first operating mode (M1) and in a second operating mode (M2). In the first operating mode, blood pressure values are based on one single measurement. In a second operating mode (M2), a mean value (S_A , D_A) of the systolic and the diastolic blood pressure is calculated on the basis of subsequent measurement values. The blood pressure monitor (1) is provided with means (2) for switching between the first operating mode (M1) and the second operating mode (M2).

M2:

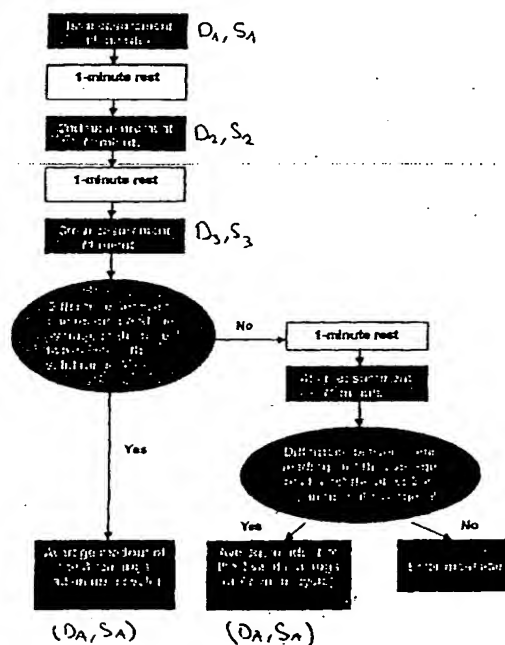


Fig. 3

EP 1 101 440 A1

Description

[0001] The invention relates to an automatic, non invasive blood pressure monitor and to a method for the non invasive measurement of the blood pressure with such a monitor according to the preamble of the patent claims.

[0002] Automatic electronic blood pressure monitors are known. These monitors determine the values of the systolic and the diastolic blood pressure e.g. on the basis of an oscillometric measurement. Other measurements are also known which are, may be based on electronic detection of Korotkoff sounds.

[0003] Automatic, electronic blood pressure measuring devices are usually applied on the upper arm of a patient, around the wrist or on a finger of the patient. While the measurement as such has proved to be sufficiently accurate with such devices, errors may be due to the fact that a user is making movements during the measurement. Ideally, the blood pressure should be taken when the user is sitting down and has been at rest for some time.

[0004] It is a disadvantage of known blood pressure measuring devices, that wrong measurement values may be given if the device is not properly used, especially if the user did not rest sufficiently before the measurement.

[0005] It is an object of the present invention to overcome the drawbacks of the prior art, especially to provide an automatic, non invasive blood pressure monitor which allows reduction of measurement errors which are based on the fact that a user is moving during the measurement or does not rest sufficiently before the measurement. A further object of the invention is to provide a method for measuring the blood pressure which allows reduction of such errors.

[0006] Still a further object of the invention is to provide a non invasive blood pressure monitor and a method for measuring the blood pressure which also allow fast determination of the blood pressure, if desired.

[0007] According to the present invention, these objects are solved with an automatic, non invasive blood pressure monitor and with a method having the features of the characterising portion of the independent patent claims.

[0008] The blood pressure monitor according to the present invention is operable in a first operating mode and in a second operating mode. In the first operating mode, blood pressure values are determined on the basis of one single measurement in a conventional manner.

[0009] In the second operating mode, the blood pressure values are calculated on the basis of a series of measurements. The inventive device can be used in the first operating mode for a quick and rough blood pressure measurement. The second operating mode allows a much more precise measurement. During a certain period of time, measurements are repeated and the val-

ue of the systolic and the diastolic blood pressure is determined as an average of several measurements. The second operating mode is especially advantageous because the measurement series lasts for a certain amount of time. While the first measurement may be still erroneous because of insufficient rest of the user, the following measurements will be more accurate because the user will normally sit or lay down during the measurements.

[0010] In a preferred embodiment, the blood pressure monitor comprises means for switching between the first operating mode and the second operating mode. The user may at its discretion choose if a fast rough measurement or slower and more accurate measurement shall be made.

[0011] The blood pressure monitor preferably comprises means for calculating or determining a statistical distribution of the measured values and means for forming an average of a number of measured blood pressure values.

[0012] The means for forming the average are preferably programmed in such a way that a weighted average may be calculated.

[0013] It must be noted, that the first and the second operating mode are independent from each other. The blood pressure monitor could only be operated in the first operating mode or in the second operating mode if this should be desired by the user. "First" and "second" does not relate to time sequences or a specific order or preference of the operating modes and it does not exclude other operating modes.

[0014] According to the method of the present invention, in the second operating mode an average value of the diastolic and the systolic blood pressure values is calculated and displayed.

[0015] In the second operating mode, a pause is preferably made between subsequent measurements. The pause can be about 60 seconds. This pause is advantageous in that it allows the measurement site (e.g. the upper arm or the wrist) to relax between measurements and in that it leads to an additional rest of the user.

[0016] In a further preferred embodiment, a statistical distribution of the blood pressure values is determined. Depending on the distribution, different calculation modes for calculating the average may be used. If one or more of the measured values substantially differs from the other measured values, a weighted average may be calculated. If all measured values are within a pre-determinable range, a normal, arithmetic average will be calculated.

[0017] In addition, if one or more of the measured values substantially differ from the others, an additional measurement may be made.

[0018] The method according to the present invention is also adapted to calculate the pulse rate with high accuracy. As the measurement lasts for quite a long time, a precise mean value of the pulse rate pressure may be calculated.

after
office
multi
Zur Station
de Messung in
Ruhelage für
hermodym. Stenofili
schon

[0019] The invention will be more clearly understood with reference to the drawings, which show:

Figure 1 a perspective representation of a blood pressure measuring device according to the invention,

Figure 2 a flow chart of the first operating mode,

Figure 3 a flow chart of the second operating mode and

Figure 4 a flow chart of the second operating mode of an alternative embodiment.

[0020] Figure 1 shows a blood pressure measuring monitor 1. The blood pressure measuring monitor 1 substantially consists of a housing 10 and a cuff 5. The housing 10 comprises a digital display 4 for displaying measurement results such as the pulse rate, the systolic blood pressure or the diastolic blood pressure. The blood pressure monitor 1 further comprises a calculating arrangement 3 for calculating the blood pressure values and the pulse rate based on the pressure P within the cuff 5. The pressure P may be measured in a conventional way with a pressure sensor (not shown).

[0021] According to the invention, the blood pressure monitor is provided with a switch 2 for switching between a first operating mode M1 (see Figure 2) and a second operating mode M2 (see Figure 3).

[0022] Additional buttons 6 are provided for resetting/turning on or off the device or starting the operation.

[0023] The blood pressure monitor 1 can be used either in the first operating mode M1 or in the second operating mode M2. In the first operating mode M1, the blood pressure measuring device is operating in a conventional manner. The value D of the diastolic blood pressure and the value S of the systolic blood pressure are measured in one single measurement cycle. This means, that the cuff is inflated once and the pressure P within the cuff is measured during one deflation cycle.

[0024] In the second operating mode, a number of measurements is made. In each of this measurements, a actual value of the diastolic blood pressure D and of the systolic blood pressure S is determined and stored within the blood pressure monitor 1. After the last of the measurements, an average value D_A of the diastolic blood pressures and an average value S_A of the systolic blood pressures is calculated in the calculating arrangement 3.

[0025] In Figure 2, a schematic representation of a measurement in the first operating mode M1 is shown. One single measurement is taken. The measurement result is immediately displayed on the display 4.

[0026] In Figure 3, a schematic representation of the second operating mode M2 is shown.

[0027] Three measurements are taken. Each measurement lasts for about 60 seconds. Between two sub-

sequent measurement, a rest of another 60 seconds is made. This is necessary because between two measurements the venous re-flow has to be settled. This usually takes a minimum time of about 60 seconds. The time might be somewhat lower (50 seconds) or, of course, somewhat longer. The three measurements lead to three values D1, S1, D2, S2, D3, S3 of the systolic and the diastolic blood pressure, respectively.

[0028] After the third measurement, a comparison of the measured values is made. If all values are within a pre-determinable range, an average D_A , S_A of the measured values is calculated.

[0029] The average of the diastolic blood pressure D_A is formed as the arithmetic average of D1, D2 and D3. The average of the systolic blood pressure S_A is formed as the arithmetic average S1, S2 and S3.

[0030] The valid range is about 20 mmHg for the systolic blood pressure and 12 mmHg for the diastolic blood pressure. This measurement cycle will take about 5 minutes.

[0031] If the measurement results of the three first measurements are not within the valid range, an additional measurement may be made. Usually, under physiological aspects, all measurement values shall be considered. Only in the case of errors due to motion artefacts or in case of an abnormal physiologic variation of the measurement results, one single result may be disregarded.

[0032] Usually, a variation of the measurement results during the three or four measurements does not necessarily lead to a rejection. People with unstable haemodynamic conditions often have systolic pressures which are outside the above mentioned pre-determinable range. Usually, these measurements are taken into consideration for calculating the average.

[0033] If the three first measurements are not within the valid range, in a first embodiment, an additional fourth measurement is made after a one minute rest. If the difference between one reading and the average of at least the other two is within the valid range, an arithmetic average of the three valid readings may be formed. This calculation leads to a seven minutes cycle. If no reading is within the valid range as compared to the average of the other two, an error message will be generated.

[0034] Usually, all artefact free results need to be accepted. If three artefact free results show a high variation (the difference between one reading and the average of the other two is outside the valid range), an additional average calculating mode may be applied (see Figure 4).

[0035] If two consecutive values are within the valid range and a third value (e.g. the first or the last one) exceeds the valid range, the third value is compared with a weighted average. If the difference between the third value and the weighted average is still outside the valid range, the first two values will be accepted and a fourth measurement will be made.

[0036] If there are no two successive valid measurements, the values will be rejected. This applies when an excessive result is between two valid measurements.

[0037] The following examples will show how different measurement results will be treated. The examples are given for systolic pressures. Similar calculations apply for the diastolic pressure.

Example 1:

[0038] S1 = 100, S2 = 100, S3 = 161

[0039] In this case, two consecutive valid values are exceeded by one abnormal value (S3). In this case, the weighted average applies.

$$A_w = \frac{((2 \cdot 100) + (2 \cdot 100) + 161)}{5} = 112$$

[0040] Since the difference between the third value and the weighted average is outside the valid range, a fourth measurement will be necessary in a similar way as shown in Figure 3.

Example 2:

[0041] S1 = 100, S2 = 161, S3 100

[0042] As there are no consecutive similar values, a non weighed average shall be formed (average = 120.33). The difference between all values and this average is outside the valid range. The whole measurement is not accepted because the patient's haemodynamic stability is not sufficient.

Example 3:

[0043] S1 = 161, S2 = 100, S3 = 100

[0044] This example is similar to example 1. The weighted average formula is applied. A fourth measurement is necessary.

Example 4:

[0045] S1 = 120, S2 = 150, S3 = 180

[0046] No consecutive values are found in this example. The normal average will be used. This patient does not have a haemodynamic stability necessary for a reasonable measurement. The average result will not be accepted and an error code will be displayed.

Example 5:

[0047] S1 = 120, S2 = 130, S4 = 140

[0048] All values are consecutive (which means there is no substantial difference between subsequent values). The normal non-weighted average is calculated. The average is 130. The difference between the average and all readings is within the valid range. An aver-

age value will be calculated and displayed.

[0049] The sequence of the measurement is schematically shown in Figure 4.

[0050] As mentioned above, errors due to artefacts are rejected. Technical artefacts may be detected on the basis of pulse analysis.

[0051] Physiologic rejections may be determined on the basis of statistic considerations.

[0052] The above algorithms show a possibility for a sophisticated calculation of an average value for the blood pressure values. This is basically possible with a blood pressure measuring device which is operatable in the first operating mode M1 (which allows fast and rough measurement) and in the second operating mode M2 (which allows a precise average measurement):

Claims

1. An automatic, non invasive blood pressure monitor (1) for indicating the diastolic and the systolic blood pressure (D_A), (S_A); (D), (S) of a patient,

characterized in that the blood pressure monitor (1) is operatable in a first operating mode (M1) and in a second operating mode (M2),

whereby in the first operating mode (M1), blood pressure values (D, S) are determined on the basis of one single measurement and

whereby in the second operating mode (M2), blood pressure values (D_A , S_A) are calculated on the basis of a plurality of measured values of the diastolic and the systolic blood pressure (D1, D2, D3, S1, S2, S3).

2. A blood pressure monitor according to claim 1, characterized in that the blood pressure monitor comprises means (2) for switching between the first operating mode (M1) and the second operating mode (M2).

3. A blood pressure monitor according to one of the claims 1 or 2, characterized in that it comprises means for calculating (3) a distribution of the values and means for forming a weighted average of the measured values (D1, D2, D3, S1, S2, S3).

4. A method for the non-invasive measurement of the blood pressure with a non-invasive blood pressure monitor, especially according to one of the claims 1 to 3, characterized in that in second operating mode (M2) and average value (D_A , S_A) of a plurality of measured values of diastolic and systolic blood pressure values (D1, D2, D3, S1, S2, S3) is calculated.

5. A method according to claim 4, characterized in that in the second operating mode (M2), a pause, preferably of about 60 seconds, is made between subsequent measurements. 5
6. A method according to one of the claims 4 or 5, characterized in that a difference between the measured values and the average of the values is formed and in that the difference is compared with a pre-determinable range. 10
7. A method according to claim 6 characterized in that a weighted average is formed for comparison if one of the measured values substantially differs from the others. 15
8. A method according to claim 7, characterized in that an additional measurement is made if the difference between the substantially differing measurement and the weighted average is outside a pre-determinable range and in that a weighted average is displayed if the difference is within the pre-determinable range. 20
9. A method according to one of the claims 4 to 8, characterized in that a pulse rate is calculated. 25

30

35

40

45

50

55

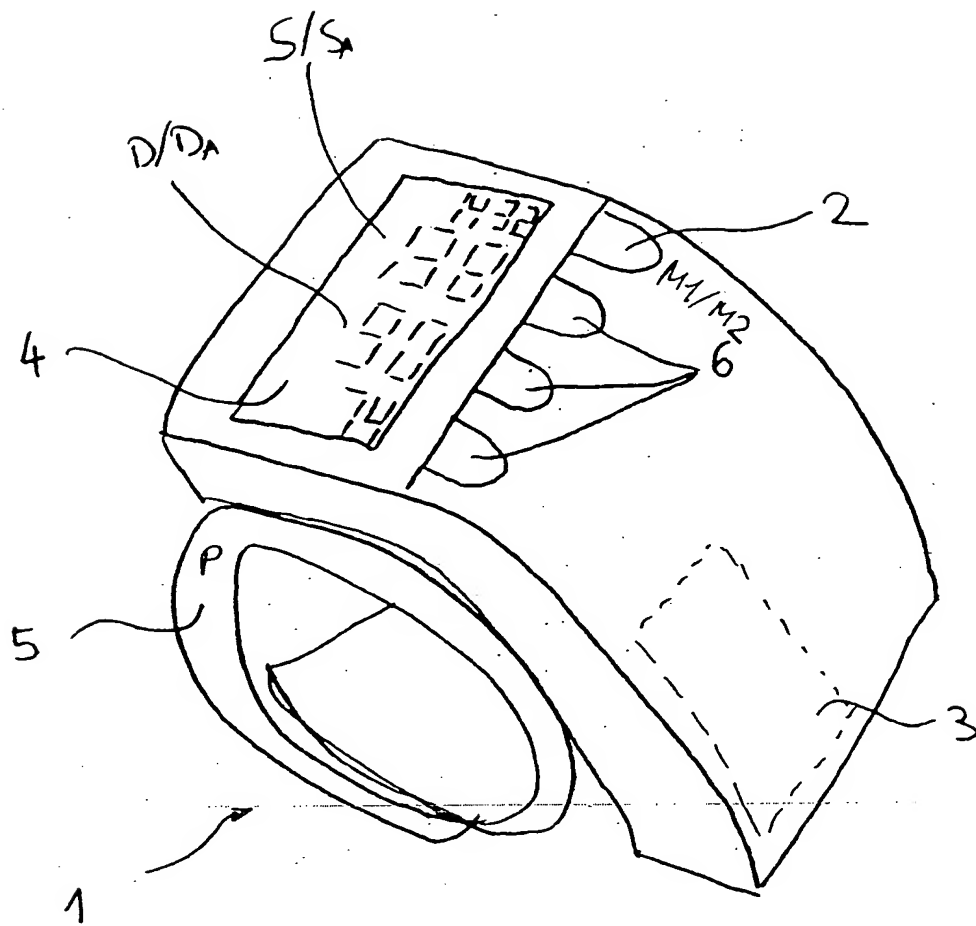


Fig-1

M1:

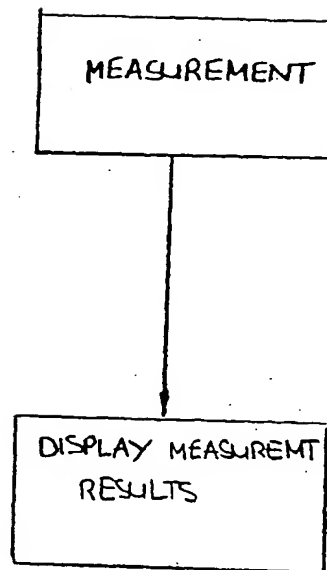


Fig.2

M2:

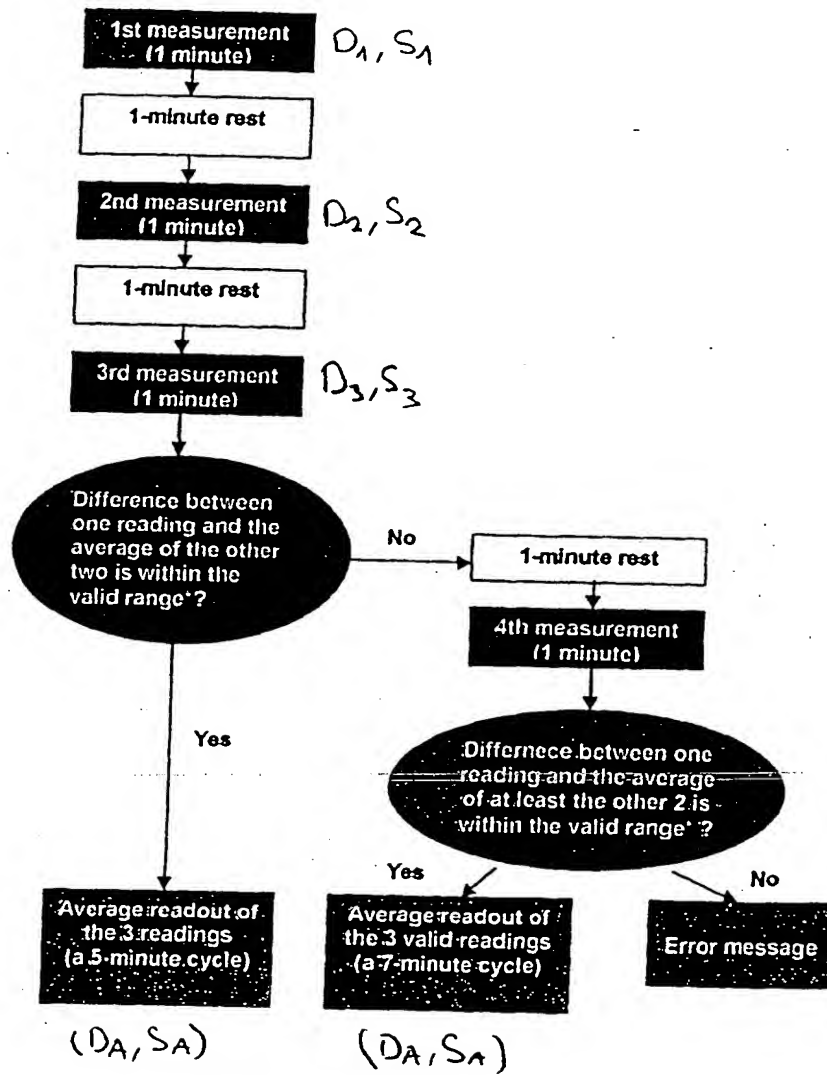


Fig. 3

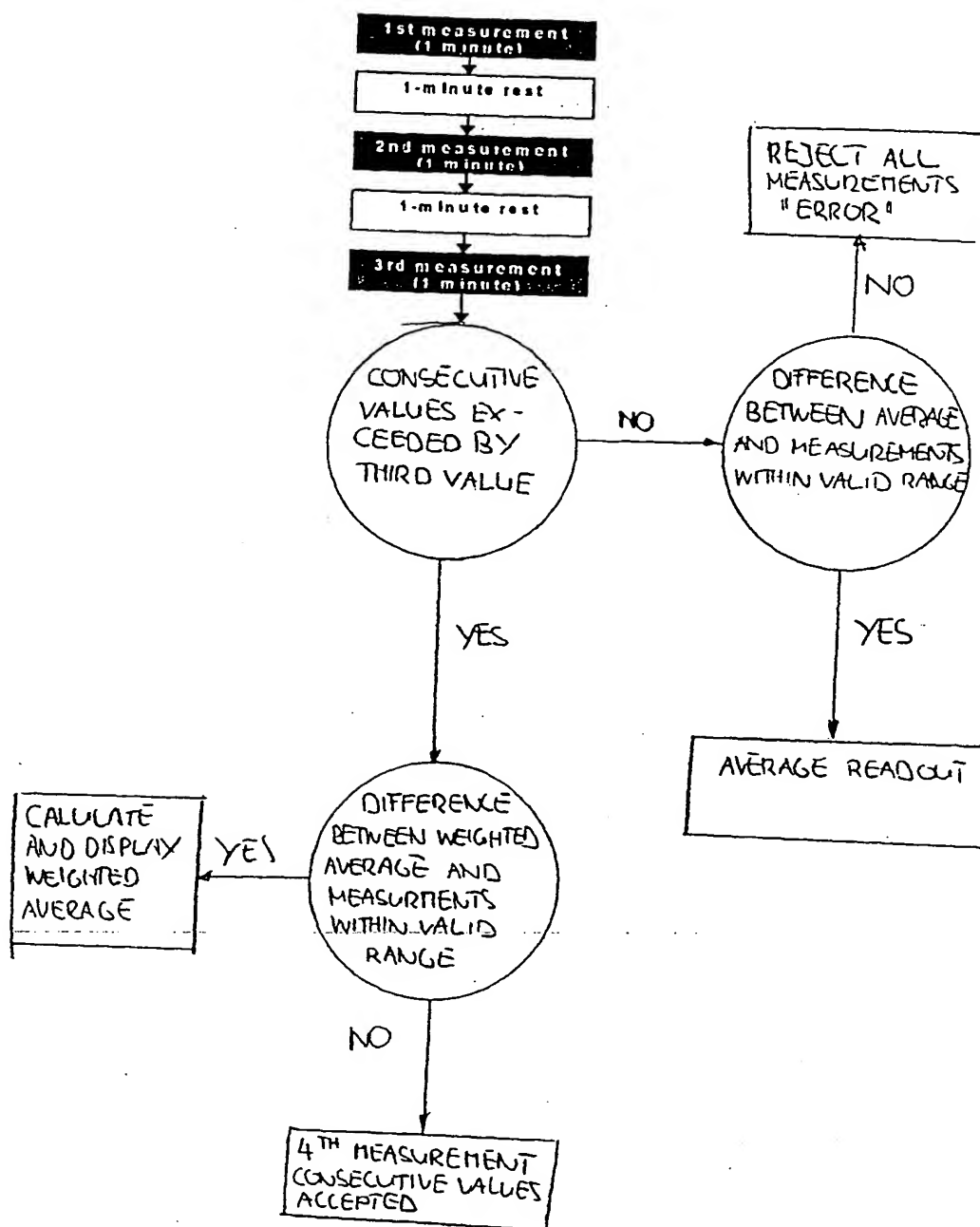


Fig. 4



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 12 2743

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 649 536 A (OGURA TOSHIHIKO ET AL) 22 July 1997 (1997-07-22) * column 21, line 42 - line 50 * * column 40, line 45 - column 41, line 12 * * column 43, line 48 - line 61 * * column 53, line 49 - column 54, line 13 *	1-5,9	A61B5/021
X	US 4 667 680 A (ELLIS DAVID M) 26 May 1987 (1987-05-26) * column 1, line 58 - column 2, line 48 * * column 3, line 46 - line 66 *	4,6-8	
A		1	
X	EP 0 536 782 A (SPACELABS INC) 14 April 1993 (1993-04-14) * column 3, line 3 - line 14 * * column 4, line 20 - line 49 * * column 8, line 53 - column 9, line 47 *	4,5,9	
A		1,6	
X	US 5 752 919 A (SCHRIMPF KATHLEEN) 19 May 1998 (1998-05-19) * column 4, line 8 - column 5, line 65 *	4	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
A		1	A61B
A	EP 0 342 249 A (HEWLETT PACKARD GMBH) 23 November 1989 (1989-11-23) * abstract *	1,4	
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 17 April 2000	Examiner Martelli, L
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 03/82 (P4/C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 12 2743

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

17-04-2000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5649536 A	22-07-1997	JP 7236616 A	12-09-1995
		JP 7236617 A	12-09-1995
		JP 7275214 A	24-10-1995
		JP 7284480 A	31-10-1995
		US 5836888 A	17-11-1998
US 4667680 A	26-05-1987	JP 1890580 C	07-12-1994
		JP 5071248 B	06-10-1993
		JP 60168432 A	31-08-1985
EP 0536782 A	14-04-1993	US 5253648 A	19-10-1993
		CA 2080297 A	12-04-1993
		US 5505206 A	09-04-1996
US 5752919 A	19-05-1998	AU 4842597 A	18-06-1998
		CA 2224831 A	17-06-1998
		EP 0850592 A	01-07-1998
EP 0342249 A	23-11-1989	JP 2019133 A	23-01-1990
		JP 2965996 B	18-10-1999
		US 4953557 A	04-09-1990

EPC FORM P/0459

For more details about this annex : see Official Journal of the European Patent Office. No. 12/82

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.